

## Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients

### **Q. What is an Emergency Use Authorization?**

A: In certain types of emergencies, the HHS Secretary may issue a [determination and declaration](#) under the Food Drug and Cosmetic Act that permits FDA to issue [emergency use authorizations](#) (EUAs) to facilitate access to [medical countermeasures](#) (drugs, biologics, vaccines, and devices) that can be used to diagnose, treat or prevent a serious disease or condition in a public health emergency.

Products authorized for use in this way may not be approved by FDA for any use, or they may be approved for other uses but not for the emergency use. FDA decides whether the use of the product is likely to be more helpful than harmful for the emergency use; i.e., the agency determines that the known and potential benefits of the medical products for their intended uses outweigh their known and potential risks. This authorization is reserved for emergency situations and is NOT the same as FDA approval or licensure.

### **Q. What does this EUA allow?**

A. The [EUA](#) allows remdesivir, manufactured by Gilead, to be distributed and used by licensed health care providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO<sub>2</sub>) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine.

### **Q. Is remdesivir approved by the FDA to treat COVID-19?**

A. No. Remdesivir is an investigational antiviral drug. It is not currently FDA-approved to treat or prevent any diseases, including COVID-19.

### **Q. Is there data showing remdesivir might benefit patients with COVID-19?**

A. In vitro (laboratory) testing of remdesivir demonstrated it is active against SARS-CoV-2 (the virus causing COVID-19). Preliminary results from a Phase 3, placebo-controlled clinical trial of remdesivir by the National Institute for Allergy and Infectious Diseases suggested that patients taking remdesivir experienced faster time to recovery as compared to patients taking a placebo. This trial included a sizeable proportion of patients who were receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) at baseline. Based on these findings, the Fact Sheet for Health Care Providers details a 10-day treatment course for patients receiving mechanical ventilation or ECMO.

Preliminary results from a different Phase 3 trial evaluating 5-day and 10-day dosing durations of remdesivir in hospitalized patients with severe COVID-19 disease reported that patients receiving a 5-day treatment course achieved similar improvement as those taking a 10-day treatment course; however, importantly, very few patients in this trial were receiving mechanical ventilation or ECMO at baseline. Therefore, based on these findings, the Fact Sheet for Health Care Providers details a 5-day treatment course for patients who are not receiving mechanical ventilation or ECMO. Patients who receive a 5-day treatment course but do not demonstrate clinical improvement are eligible to continue to receive remdesivir for an additional 5 days.

The safety and efficacy of remdesivir for the treatment of COVID-19 are being evaluated in multiple ongoing clinical trials.

Because remdesivir may possibly help very sick patients, FDA is allowing this drug to be provided to hospitalized patients with severe COVID-19 under an [EUA](#) issued May 1, 2020. Under the EUA, [health care providers](#) and [patients](#) are provided with information about the risks of remdesivir. However, final data from clinical trials included in an FDA application are necessary for us to determine whether the drug is safe and effective in treating or preventing COVID-19.

**Q. Are there clinical trials underway evaluating remdesivir for COVID-19?**

A. Yes. [Clinical trials](#) are completing to determine if remdesivir can benefit patients with COVID-19 infection. Additional trials may be planned in special populations such as patients with kidney problems or use of remdesivir with other drugs to treat COVID-19.

The [EUA](#) includes a [fact sheet](#) for health care providers that contains additional information about results from clinical trials for remdesivir.

**Q. Are there side effects of remdesivir?**

A. Possible side effects of remdesivir are:

- Infusion-related reactions. Infusion-related reactions have been seen during a remdesivir infusion or around the time remdesivir was given. Signs and symptoms of infusion-related reactions may include: low blood pressure, nausea, vomiting, sweating, and shivering.
- Increases in levels of liver enzymes, seen in abnormal liver blood tests. Increases in levels of liver enzymes have been seen in people who have received remdesivir, which may be a sign of inflammation or damage to cells in the liver.

These are not all the possible side effects of remdesivir. Remdesivir is still being studied so it is possible that all of the risks are not known at this time.

**Q. How can remdesivir be obtained for use under the EUA?**

A. HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR) [announced](#) the allocation plan for remdesivir. Gilead donated vials of the investigational antiviral drug remdesivir to treat hospitalized COVID-19 patients with severe disease in areas of the country hardest hit by the pandemic. State health departments will distribute the doses to appropriate hospitals in their states because state and local health departments have the greatest insight into community-level needs in the COVID-19 response. Healthcare providers interested in administering the donated remdesivir in accordance with the authorized use under the EUA should contact their state health department. More information about allocation of remdesivir can be found [here](#).

Outside of the EUA, remdesivir remains available through [Emergency investigational new drug applications \(EINDs\)](#) for pregnant women and children if they cannot gain access to remdesivir via the EUA.

**Q. Is there a requirement for providers to report side effects as part of the EUA?**

A. Yes. As part of the EUA, FDA is requiring health care providers who prescribe remdesivir to report all medication errors and serious adverse events considered to be potentially related to remdesivir through FDA's [MedWatch Adverse Event Reporting](#) program. Providers can complete and submit the report [online](#); or download and complete the [form](#), then submit it via fax at 1-800-FDA-0178. This requirement

is outlined in the EUA's health care provider [fact sheet](#). FDA MedWatch forms should also be provided to Gilead.

**Q. Do patient outcomes need to be reported under the EUA?**

A. No, reporting of patient outcomes is not required under the EUA. However, reporting of all medication errors and adverse events considered to be potentially related to remdesivir occurring during remdesivir treatment is required.

**Q. Does the EUA permit remdesivir to be used to prevent COVID-19?**

A. No. Remdesivir is allowed for use through the EUA for the *treatment* of hospitalized patients with severe COVID-19, but not for *prevention*.

**Q. Does the EUA permit remdesivir to be used outside the hospital (non-hospitalized patients)?**

A. No. The EUA is only for hospitalized patients with severe COVID-19, therefore the EUA does not allow for use outside of a hospital setting.

**Q. How does this EUA add to/differ from the existing Expanded Access approval?**

A. An Emergency Use Authorization is a temporary measure, pursuant to a Secretary of Health and Human Services declaration, in which the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear (CBRN) threat agents. In issuing an EUA, the FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by the CBRN agent, that the known and potential benefits outweigh the known and potential risks for the product, and that there are no adequate, approved, and available alternatives.

On May 1, 2020, FDA granted Gilead's EUA request allowing remdesivir to be distributed and used by licensed health care providers to treat adults and children hospitalized with severe COVID-19. For the purposes of this EUA, severe COVID-19 is defined as patients with an oxygen saturation (SpO<sub>2</sub>) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine. FDA's emergency use authorization for remdesivir is subject to the scope and conditions as detailed in the [letter of authorization](#).

While EUAs may only be issued while the Secretary of Health and Human Services declaration justifying emergency use is effective, requests for expanded access to an investigational drug may be submitted to FDA and considered at any time. Expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Expanded access requires submission of an expanded access protocol to an existing investigational new drug application (IND) or a new expanded access IND, and is subject to certain IND requirements, such as IND safety reporting.

For remdesivir, the following mechanism may be available for expanded access:

- Treatment under an [emergency investigational new drug applications \(EINDs\)](#)

- Pregnant women who are not receiving treatment at medical centers that are participating in Gilead’s expanded access protocol
- Children younger than 12 years of age OR children who are not receiving treatment at medical centers that are participating in Gilead’s expanded access protocol

For more information about expanded access to remdesivir, please contact Gilead or refer to the following webpage: [Emergency Access to Remdesivir Outside of Clinical Trials](#).

**Q. Can health care providers share the patient/caregiver Fact Sheet electronically?**

A. The letter of authorization for remdesivir requires that Fact Sheets be made available to healthcare providers and to patients/caregivers, “through appropriate means.” Electronic delivery of the Fact Sheet is an appropriate means, for example, when the patient requests it electronically, the Fact Sheet is delivered as a PDF (not a URL), and the patient is able to obtain access to the electronic version prior to receiving the medicine. Additionally, health care providers should confirm receipt of the fact sheet with the patient. Paper copies must be available for patients who request them.

**Q. What is FDA doing to facilitate the development and expedite the review of remdesivir?**

A. On March 26, 2020, FDA granted Fast Track designation to Gilead for remdesivir, which among other things, maximizes the opportunities for Gilead to engage with the Agency on its development of remdesivir for the treatment of COVID-19.

Based on this designation, on April 6, 2020, FDA granted Gilead’s request and accepted its proposal to allow for a rolling review of its development program for remdesivir. Under this process, Gilead may submit and FDA will review sections of Gilead’s planned New Drug Application (NDA) for remdesivir as they arrive. Under traditional processes, FDA’s review of an NDA does not begin until the sponsor has submitted the entire application to the Agency.

Additionally, FDA has authorized use of remdesivir through an [Emergency Use Authorization](#) for certain hospitalized patients with severe COVID-19 disease while Gilead’s development program remains underway.